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# PHARMACOECONOMICS IN FORMULARY DECISION MAKING

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## ABSTRACT

**OBJECTIVES** To assess the knowledge of pharmacoeconomic (PE) information in patient groups, healthcare professionals, Government Formulary List Advisory Committee (GFLAC) and Pharmaceutical Research Based Industry Malta Association (PRIMA) members, to determine the extent to which PE information is used in formulary decision making and to define the specific challenges to adapt and establish the PE concept locally.

**METHOD** A cross sectional study was conducted to investigate local PE knowledge and trend of use. A structured questionnaire was drafted. The questionnaire was distributed electronically to GFLAC members, health care professionals, patient groups and PRIMA members. A review of international PE guidelines was carried out followed by development of another questionnaire to obtain feedback from experienced Health Technology Assessment (HTA) and PE units in European countries. This questionnaire was disseminated to European organisations after obtaining permission to use 33 European countries listed on the International Society for Pharmacoeconomics Organisation (ISPOR) and the European Network for Health Technology Assessment (EUnetHTA) mail lists.

**KEY FINDINGS** Forty out of a total of 74 electronically distributed questionnaires (response rate 54%) were returned. With regards to formulary decision making, the most influential profession was that of physicians whilst the most influential factors were drug efficacy and drug safety. The majority of participants are in favour of PE being required in formulary decision making. A total of 15 replies from 13 different European agencies were obtained. The majority of respondents agreed that Malta should adopt its own system of PE assessment. A further suggestion addressed the adaptation and tailoring of an existing national system and application of pharmacoeconomics in special cases.

**CONCLUSION** Results obtained in this study indicate that the concept of pharmacoeconomics should be required in formulary decision making and that Malta would benefit from adopting its own system of PE assessment.

**KEYWORDS** Pharmacoeconomics, Formulary Decision Making, Pharmacoeconomic Guidelines

## INTRODUCTION

Decision-makers at all levels of the health care system have been faced with increasing pressure to make more efficient use of existing health care resources.<sup>1</sup> As a result, public and private agencies worldwide have turned to evidence-based processes to improve assessment of the clinical and economic benefits of new and existing health care technologies. Although safety and efficacy are essential first considerations, Health Technology Assessments (HTAs) and economic evaluation, have become an integral component of the overall decision making process. An important subset of health economics is pharmacoeconomics which focuses solely on pharmaceuticals.<sup>2</sup> This concept is applied to guide the use of limited resources to yield maximum value to patients, healthcare payers and society.

Locally, availability of medicinal products within the Government Health Services is regulated by Legal Notice 58 of 2009 of the Medicines Act. Although the Directorate for Pharmaceutical Affairs within the Ministry for Health processes HTAs, no governmental entity is responsible for PE assessments. The aims of this study were to assess the knowledge of PE information in patient groups, healthcare professionals, GFLAC and PRIMA members, to determine the extent to which PE information is used in formulary decision making and to define the specific challenges to adapt and establish the PE concept in Malta.

## METHOD

A cross-sectional study was conducted to investigate local PE knowledge and trend of use. A structured questionnaire was drafted based on a 2010 study by Alsultan.<sup>3</sup> The questionnaire was pre-tested for face and content validity by 10 pharmacists experienced in the Government Formulary List. The questionnaire was distributed electronically to GFLAC and PRIMA members, health care professionals and patient groups. The questionnaire covered the following issues: influence of different professions in formulary decision making, potential use and helpfulness of PEs in the formulary decision making process, respondents' understanding of PE data, and barriers in the use of PEs and future expectations in formulary decision making.

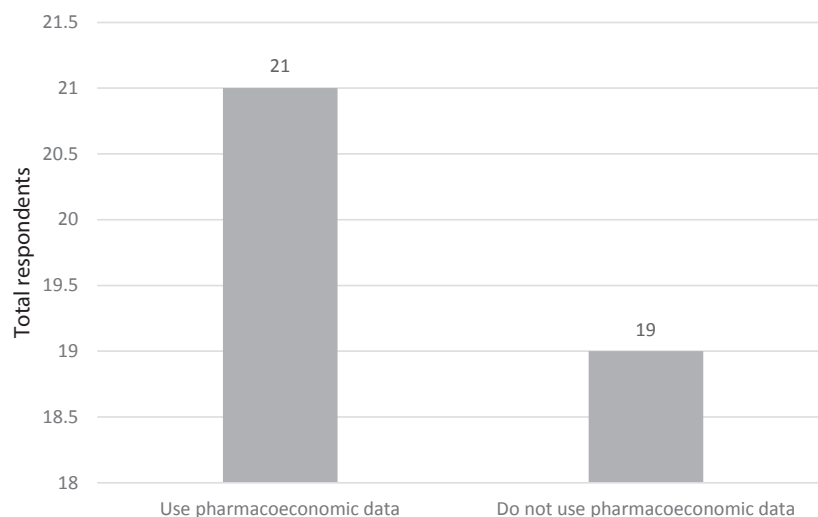
In the second part of the study a review of international PE guidelines was undertaken to determine the specific



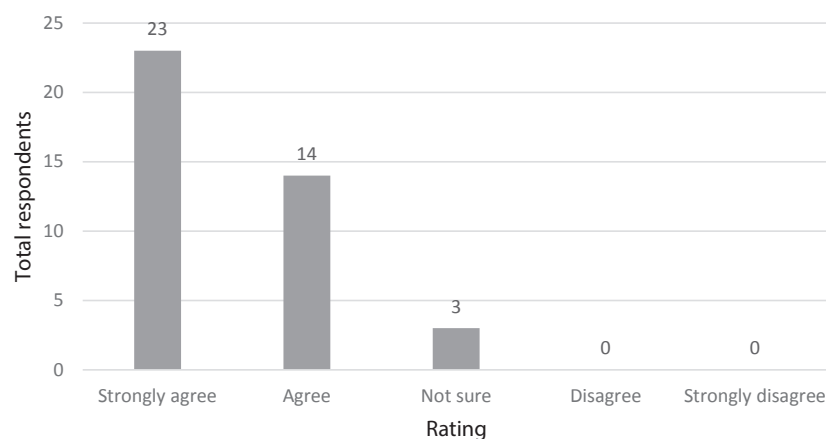
challenges to adapt and establish the pharmacoeconomic concept. Eligibility criteria for inclusion required guidelines to be European, in the English language and published from 2003 onwards. The International Society of Pharmacoeconomics and Outcome Research (ISPOR) was contacted and the investigator (SMS) was invited to use the ISPOR HTA Road Maps and PE Guidelines tools<sup>4</sup> which were relevant for the study. Feedback was obtained from experienced PE units in European countries through another questionnaire. A questionnaire based on a previous Health Working Paper by the Organisation for Economic Co-operation and Development (OECD)<sup>5</sup> was prepared. The draft questionnaire was pre-tested by 10 pharmacists for face and content validity. After obtaining permission from ISPOR and the European Network for Health Technology Assessment (EUnetHTA)<sup>6</sup>, the questionnaire was electronically disseminated to various European organisations. Topics included in the questionnaire were: the primary conceptual basis for the use of PE assessment, methods used for selecting new products and comparators for PE assessment, the accomplishments reached using PE, benefits of European co-operation for PE assessment and whether Malta would benefit from adopting its own system of PE assessment.

## RESULTS

In the first part of the study, a total of 74 questionnaires were distributed; 40 responded with the majority being females (n=21), and the age range was between 41-55 years. Most respondents were from the pharmaceutical profession (n=11). Formulary decision making, the most influential profession was found to be that of physicians (n=36) whilst drug efficacy (n=36) and drug safety (n=36) were the most influential factors. Out of these 40 respondents, 21 used pharmacoeconomic data (Figure 1). Out of these 21 respondents who use PE data, 13 rated PE data as extremely helpful or very helpful, 12 used more than one type of PE data source and 11 rated themselves as somewhat knowledgeable in the understanding of PE data. Figure 2 indicates that the majority (n=37) of participants are in favour of PE being required in formulary decision making as in other countries.



**Figure 1:** Use of Pharmacoeconomic Data (N=40)



**Figure 2:** Pharmacoeconomics in Formulary Decision Making as in other countries (N = 40)

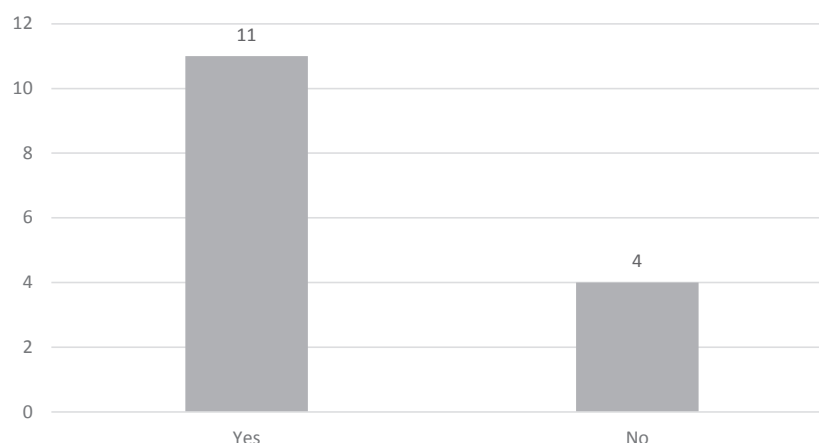
In the second part of the study, where the specific challenges to adapt and establish the PE concept were analysed, the ISPOR website has provided access to PE guidelines that are available internationally. Guidance documents are dated on the basis of publication and are categorised as: PE Recommendations, PE Guidelines, and Submission Guidelines.<sup>5</sup>

A total of 15 replies from 13 different European agencies were obtained, the majority replying on an 'own opinion' basis (n=14). Four other agencies stated that they could not participate as they do not produce PE assessments (Table 1). The primary conceptual basis for the use of PE assessment is value for money for 8 agencies, Governmental entities are

responsible for processing or conducting PE assessments in 6 agencies and pharmaceutical companies are responsible for submitting the initial PE assessment for 11 agencies. All new products are eligible in the selection of pharmaceuticals for PE assessment for 8 agencies. Overall responding agencies positively agreed that PE assessments reduced total drug expenditure (n=11), reduced unnecessary drug use (n=9), improved prescribing cost effectiveness (n=8), and sensitised drug manufacturers to the need for effective drugs (n=8).

European Agency	Country
Main Association of Austrian Social Security Institutions	Austria
Health Research for Action	Belgium
National Institute for Quality and Organisational Development in Healthcare and Medicines	Hungary
National Centre for Pharmacoeconomics	Ireland
Health Information and Quality Authority	
National Health Services	Latvia
State Health Care Accreditation Agency	Lithuania
Agency for Health Technology Assessment	Poland
Health Technology Assessment (HTA) Consulting	Poland
Scottish Medicines Consortium	Scotland
Andalusian HTA Agency	Spain
University Hospital of Geneva	Switzerland
Dutch Health Care Insurance Board/Dutch Health Care Institute (now <i>National Health Care Institute</i> )	The Netherlands

**Table 1:** Feedback from experience PE Units in Europe



**Figure 3:** Malta adopting own PE system (N = 15)

A positive attitude was observed towards European co-operation and agreement since it strengthens the role of international agencies (n=12), may create mutually agreed guidelines (n=12), may create a standard format for companies to follow when submitting assessments (n=11), supports periodic discussion meetings to discuss assessment issues (n=11), facilitates communication among national assessment groups (n=12).

Figure 3 indicates that the majority (n=11) of respondents agree that Malta should adopt its own system of PE assessment. Other feedback and suggestions include to clarify the process and disseminate information on the chosen criteria to concerned clinicians, industry and policy makers, adapt and tailor an existing national system to be more efficient and to apply PE in special cases, as Malta is a small country with limited bargaining power over pharmaceutical companies.

## DISCUSSION

The overall local results are comparable and consistent with a study conducted by Alsultan<sup>3</sup>, although in this study the target population included also representatives from patients and the pharmaceutical industry. When developing a PE approach to formulary development, the inclusion of experienced professionals, including pharmacists, who understand PE and who can analyse and convert data into useful information is considered to be critical.<sup>7</sup> In the early 1990s, Australia announced that economic analyses would be a submission requirement. Since then this policy has spread worldwide. Whilst feedback from European organisations was critical, overall results were still consistent with the 2003 OECD report<sup>4</sup>. Both the ISPOR and EUnetHTA were essential in providing a communication link with European organisations involved in PE assessments. Pressure on healthcare budgets has increased so much that harmonisation requirements for HTA across Europe has become a political priority at EU level. The European Commission is contributing millions of euro to the EUnetHTA initiative; an HTA collaboration with EU member states, amongst them Malta. This is in line with EU Cross-Border Healthcare Directive.<sup>8</sup>

## CONCLUSION

The trend appears to be that more jurisdictions, rather than fewer, are using economic analysis as part of their decision making procedures.<sup>9</sup> Economic efficiency and maximising health outcomes for a given total budget is too often sacrificed in the pursuit of cost containment. The adoption of policies that take us beyond the drug budget silo mentality should be encouraged. The findings and feedback obtained from local and European respondents in this research is clearly in favour of the adaptation of the pharmacoeconomic concept in formulary decision making in Malta. Further research is required to identify the type of guidelines and methods which would be most suitable to the local scenario.

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